

What is claimed is:

- 5 1. A pharmaceutical composition useful for the treatment or control of bacterial infections by parenteral administration, the composition comprising effective amounts of (a) piperacillin or a pharmaceutically acceptable salt thereof, (b) tazobactam or a pharmaceutically acceptable salt thereof and an aminocarboxylic acid chelating agent or a pharmaceutically acceptable salt thereof.
- 10 2. A pharmaceutical composition according to claim 1 further comprising a buffer adapted to maintain a pH within the range of 6.0 to 7.5.
3. A pharmaceutical composition according to claim 2 wherein the buffer is adapted to maintain a pH of substantially 6.5.
- 15 4. A pharmaceutical composition according to claim 2 wherein the buffer is citrate.
5. A pharmaceutical composition according to claim 1 containing piperacillin sodium, tazobactam sodium and a sodium salt of the aminocarboxylic acid chelating agent.
- 20 6. A pharmaceutical composition according to claim 5 further comprising sodium citrate as buffer.
- 25 7. A pharmaceutical composition according to any one of claims 1 to 6 wherein the aminocarboxylic acid chelating agent is at least one compound selected from the group consisting of ethylenediaminetetraacetic acid (EDTA), diethylenetriaminepentaacetic acid (DTPA), hydroxyethylenediaminetriacetic acid (HEDTA), nitrilotriacetic acid (NTA), O,O'-bis(2-aminoethyl)ethyleneglycol-N,N',N'-tetraacetic acid (EGTA), trans-1,2-diaminocyclohexane-N,N',N'-tetraacetic acid (CyDTA) and the pharmaceutically acceptable salts thereof.

8. A pharmaceutical composition according to claim 7 wherein the aminocarboxylic acid chelating agent is selected from ethylenediaminetetraacetic acid (EDTA) and the pharmaceutically acceptable salts thereof.
- 5 9. A pharmaceutical composition according to any one of claims 1 to 8 further comprising an aminoglycoside.
- 10 10. A pharmaceutical composition according to claim 9 wherein the aminoglycoside is selected from amikacin and tobramycin.
11. A pharmaceutical composition according to any one of claims 1 to 10, the pharmaceutical composition being in the form of a powder that can be reconstituted by addition of a compatible reconstitution diluent prior to parenteral administration.
- 15 12. A pharmaceutical composition according to any one of claims 1 to 10 in the form of a frozen composition adapted to be thawed and, if desired, diluted with a compatible diluent prior to parenteral administration.
13. A pharmaceutical composition according to any one of claims 1 to 10 in a form ready to use for parenteral administration.
14. A pharmaceutical composition according to any one of claims 1 to 13 in the form of a solution.
- 20 15. A pharmaceutical composition according to claim 14 wherein the concentration of piperacillin is within the range of from about 8 mg/ml to about 500 mg/ml of solution.
- 25 16. A pharmaceutical composition of claim 14 or 15 wherein the concentration of the citrate buffer is within the range of from 0.25 mg/ml to 25 mg/ml of solution.
17. A pharmaceutical composition according to any one of claims 14 to 16 wherein the concentration of tazobactam is within the range of 0.1 mg/ml to 125 mg/ml of solution.

18. A pharmaceutical composition according to any one of claims 1 to 17 further comprising an effective amount of dextrose to render the composition physiologically isosmotic.
- 5 19. A pharmaceutical composition according to claim 14 to 17 further comprising dextrose within the range of from about 5 mg/ml to about 100 mg/ml of solution.
20. A pharmaceutical composition according to any one of claims 14 to 19 containing amikacin within the range of 0.1 mg/ml to 75 mg/ml of solution.
- 10 21. A pharmaceutical composition according to any one of Claims 14 to 20 containing tobramycin within the range of 0.1 mg/ml to 75 mg/ml.
22. A pharmaceutical composition according to any one of claims 14 to 21 wherein the aminocarboxylic acid chelating agent or a pharmaceutically acceptable salt thereof is in the range of about 0.002 mg/ml to about 10 mg/ml.
- 15 23. A pharmaceutical composition according to claim 22 wherein the aminocarboxylic acid chelating agent or a pharmaceutically acceptable salt thereof is in the range of about 0.003 mg/ml to about 1 mg/ml.
- 20 24. A pharmaceutical composition according to claim 1 or 2 wherein said pharmaceutical composition is a dose concentrate in a sealed container wherein said container has a space sufficient for introduction of a volume of aqueous solvent sufficient to form a concentrated solution of said pharmaceutical composition.
- 25 25. A pharmaceutical composition according to claim 1 or 2 wherein said pharmaceutical composition is contained in a liquid as a unit dose IV bag or IV bottle for intravenous administration for the treatment of bacterial infections.
26. A pharmaceutical composition according to claim 1 containing (a) piperacillin or a pharmaceutically acceptable salt thereof in an amount of substantially 4.0 g calculated as piperacillin free acid, (b) tazobactam or a

pharmaceutically acceptable salt thereof in an amount of substantially 0.5 g calculated as tazobactam free acid, (c) substantially 1 mg of EDTA or of a pharmaceutically acceptable salt of EDTA and (d) substantially 100 ml of water for injection.

- 5           27. A pharmaceutical composition according to claim 26 containing (a) piperacillin sodium equivalent to 4 g piperacillin free acid, (b) tazobactam sodium equivalent to 0.5 g of tazobactam free acid, (c) substantially 1 mg of a sodium salt of EDTA and (d) substantially 100 ml of water for injection.
- 10           28. A pharmaceutical composition according to claim 26 or 27 further comprising substantially 0.2 g of sodium citrate as buffer.
29. A pharmaceutical composition according to any one of claims 26 to 28, further comprising substantially 2.0 g of dextrose.
- 15           30. A pharmaceutical composition according to any one of claims 26 to 29, further comprising substantially 500 mg amikacin.
31. A pharmaceutical composition according to any one of claims 26 to 30, further comprising substantially 160 mg of tobramycin.
32. A pharmaceutical composition in the form of a powder that can be reconstituted by addition of a compatible reconstitution diluent to form a composition as claimed in any one of claims 26 to 31 prior to parenteral administration.
- 20           33. A pharmaceutical composition according to any one of claims 26 to 31 in the form of a frozen composition adapted to be thawed and, if desired, diluted with a compatible diluent prior to parenteral administration.
- 25           34. A process for the manufacture of a pharmaceutical composition useful for the treatment or control of bacterial infections by parenteral administration, the pharmaceutical composition being in the form of a powder that can be reconstituted by addition of a compatible reconstitution diluent prior to parenteral administration or in the form of a

5 frozen composition adapted to be thawed and, if desired, diluted with a compatible diluent prior to parenteral administration; which process comprises freezing or freeze-drying a solution containing effective amounts of (a) piperacillin or a pharmaceutically acceptable salt thereof, (b) tazobactam or a pharmaceutically acceptable salt thereof and an aminocarboxylic acid chelating agent or a pharmaceutically acceptable salt thereof in an aqueous vehicle.

10 35. A method for the treatment or control of bacterial infections in a mammal wherein the method comprises parenteral administration of a therapeutically effective amount of the pharmaceutical composition of claim 13 to said mammal.

15 36. A method for the treatment or control of bacterial infections in a mammal wherein the method comprises parenteral co-administration of a therapeutically effective amount of the pharmaceutical composition of claim 13 and an aminoglycoside to said mammal.

37. The method according to claim 36 wherein the aminoglycoside is selected from amikacin and tobramycin.